

PSJ15 Exh 55

Message

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**From:** Webb, Kevin J [Kevin.Webb@mallinckrodt.com]  
**Sent:** 10/5/2016 4:49:35 PM  
**To:** Tyndall, Mark [Mark.Tyndall@mallinckrodt.com]; Naten, Derek [Derek.Naten@mallinckrodt.com]; Long, Erika [Erika.Long@mallinckrodt.com]; Malasi, Julian F [Julian.Malasi@mallinckrodt.com]; Stauder, Nancy R [Nancy.Stauder@mallinckrodt.com]; Gouveia, Staci [Staci.Gouveia@mallinckrodt.com]; Sciarra, Rhonda [Rhonda.Sciarra@mallinckrodt.com]  
**CC:** Randon, Breon [Breon.Randon@mallinckrodt.com]; Jackson, Catherine [Catherine.Jackson@mallinckrodt.com]  
**Subject:** For Review: Pending ADF Roxicodone FDA Submission

Team,

The other day, Nancy and I participated in a call with the Generics team regarding the pending submission of an NDA to the FDA for an Abuse Deterrent Formulation (ADF) Roxicodone. Pending approval, Mallinckrodt would then introduce an authorized generic, making Roxicodone the first generic on the market with abuse deterrent technology. This is a significant game changer, and creates Communications and GA/Advocacy opportunities for MNK.

Please review the meeting notes below. I'll schedule a call for us to debrief and discuss next steps.

Thanks.

Kevin

**Background**

- MNK plans to file NDA for re-formulated ROXICODONE® (oxycodone hydrochloride, immediate release) with ADF on Nov 30
  - ROXICODONE (Roxi) is MNK branded formulation of oxycodone. Other common brand name is Oxycontin (Purdue Pharma)
  - New ADF formulation will contain 5 dosage strengths(5mg, 10mg, 15mg, 20mg, & 30mg), which is two additional strengths from current portfolio
- As the holders of the Roxi NDA, MNK is one of 13 manufacturers providing a generic product in the oxycodone market; Branded drug has less than 1% share
- Oxycodone immediate release (IR) is the most abused opioid on the market, and the most abused product in MNK's portfolio
- MNK market share of the generic Roxi market is 13-15%
- Cost per 100 count bottle is ~\$10/bottle (very low price)

**New Abuse Deterrent Formulation (ADF)**

- Effervescence (patent pending): generates a noxious bubbling sensation when snorted
- Gelling: Prevents ability to syringe

**NDA Submission**

- Roxi is only generic for which MNK will develop ADF (since it is the only MNK owned referenced drug NDA)
- MNK will request expedited review (at Nov 10 requested FDA meeting); TBD is if MNK will request a separate Ad Comm review?
- Priority Review Launch: July 2017; Standard Launch: September 2017
- Potential concern is product failed to meet one of its primary end points (Drug Liking). But all other end points were exceeded, which validated that recreational drug users did not like to snort/inject the re-formulated Roxi

**Launch of Re-formulated Roxi**

- Following approval, MNK will immediately introduce an authorized generic (ANDA) of the new re-formulated Roxi
- New authorized generic will be priced as generic (~\$40-\$50/ 100 count bottle)
- Request FDA to pull the NDA of the original non-ADF Roxi IR opioid due to safety reasons. If successful, this would require all other generic formulations to be removed from the market as well; possible FDA would pull original NDA proactively
  - (NOTE: Took Purdue 3 years to gather the necessary post-approval safety data to move the FDA to pull all other generic formulations of Oxycontin from the market; Endo tried the same with Opana ER but never succeeded)
  - (Since MKT has limited Roxi generic market share, could be difficult to collect the necessary safety data to convince the FDA to pull the other non-ADF generics – considering working with Kaiser, Walmart and DoD)
- Though unit price will be higher than current generic formulation, WAC will stay consistent, so patients should not see a rise in co-pay (tier 1 generic). However, this is dependent upon how plans decide to tier the product. But compared to branded ADF's, this will be significantly less expensive

#### **Next Steps**

- Brand the new ADF technology. TBD is how/what name? (Reviewing other ADF technologies that have been branded)
- Implement a contract strategy with wholesalers/distributors (including retail pharmacies) for sole source agreement to supply only generic formulation of IR Oxycodone with ADF
  - (Our current pouch campaign with Walmart might help create additional partnership opportunities for the ADF Roxi)
- This will be first generic opioid on the market with ADF. What type of communication and policy/advocacy outreach could be done?
- Determine what level of pre-approval awareness MNK can undertake with policy makers; legislators and/or payers/contracts.

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